Relationships between unmet needs, depression and anxiety in non-advanced cancer patients

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Abstract

Introduction: In oncology settings, less attention is given to patients' unmet need and to existential and emotional distress, compared to physical symptoms. We aimed to evaluate correlations between unmet needs and emotional distress (self-reported anxiety and depression) in a consecutive cohort of cancer patients. The influence of socio-demographic and clinical factors was also considered.

Methods: Three hundred cancer patients recruited from an out-patient Supportive Care Unit of a Comprehensive Cancer Centre completed the Need Evaluation Questionnaire (NEQ) and the Edmonton Symptom Assessment System (ESAS). Unmet needs covered five distinct domains (informational, care/assistance, relational, psycho-emotional and material).

Results: After removal of missing data, we analysed data from 258 patients**.** Need for better information on future health concerns (42%), better services from the hospital (43%), and to speak with individuals in the same condition (31%) were the most frequently reported as unmet. Based on the ESAS, 27.2% and 17.5% of patients respectively had a score of anxiety or depression > 3 and needed further examination for psychological distress. Female patients had significantly higher scores for anxiety (p<.001) and depression (p=.008) compared to males. Unmet needs were significantly correlated with both anxiety (r_s=.283) and depression (r_s=.284). Previous referral to a psychologist was significantly associated with depression scores (p=.015). Results were confirmed by multiple regression analysis.

Conclusions: Screening for unmet needs whilst also considering socio-demographic and clinical factors, allows early identification of cancer patients with emotional distress. Doing so will enable optimal management of psychological patient-reported outcomes in oncology settings.

Keywords: Cancer; patient-centered care; supportive care; unmet needs; anxiety; depression

Introduction

Few resources are allocated to support research on the wellbeing of patients diagnosed with cancer, and to specifically investigate aspects going beyond physical problems associated with the disease and its treatment, such as psychosocial outcomes, spiritual concerns and unmet needs (1, 2). Diagnosis of cancer, however, not only affects an individual physically, but also causes problems at an emotional level. It engenders anxiety and emotional distress related both to possible disease progression and a potentially shortened lifespan (3), and uncertainty about changes to social role, body image or treatment options (4) and so forth.

After their diagnosis, cancer patients often have trouble in dealing with, and in adapting to daily life. Distress may stem from many different causes, but may include surgical and treatment experiences, extending to the management of acute pain, toxic treatment regimens, financial burdens of care, and potential detrimental effects and disruptions of personal and professional lives (5). Consequently, cancer is associated with an increased risk of psychiatric disorders such as major depression and adjustment disorders (6-9).

Patients who undergo cancer treatment frequently report emotional and physical symptoms lasting years after the initial cancer diagnosis, some of which may even arise months or even years after the treatments are completed (10-12). Comorbid psychological distress is often present and is associated with socio-demographic and cultural factors, in addition to organizational and contextual factors related to where patients receive care (13). Thus, it is important to both (i) improve the ability of medical oncologists to recognize abnormal anxiety and/or depression and (ii) to increase the availability of psychological care and supportive and informative facilities for patients throughout their treatment. At the same time, it is important to directly investigate factors associated with psychological distress, in order not only to define cancer treatments tailored on the distinct tumor

molecular characteristics, but also to develop and plan supportive interventions for cancer patients tailored to their specific unmet needs and individual circumstances (14).

In particular, given the well-known, albeit variable, levels of emotional distress (15) and unmet needs among cancer patients (16), it is important to better understand the link between unmet needs and emotional distress, especially the more clinically important outcomes of depression and anxiety. Variability in the prevalence of unmet needs and emotional distress reported among different studies to date could be due, among other reasons (e.g. use of different assessment tools) to the inclusion of patients with different socio-demographic and clinical characteristics. Therefore, besides the simple correlation of patients' needs and distress, a better knowledge of which individual variables affect such measures will make it possible to predict which subgroups of cancer patients are more at risk of developing emotional problems and behavioral sequelae. Recognizing such problems early would allow a timely intervention to reduce the emotional burden of cancer.

This study, carried out on a sample of outpatients attending a Supportive Care Unit in a Comprehensive Cancer Centre for the first time, evaluated the influence of socio-demographic and clinical factors on the prevalence of unmet needs and emotional distress. We also explored statistical correlations between anxiety, depression and unmet needs.

Methods

Participants and recruitment

This is a cross-sectional observational study carried out on cancer patients attending the Supportive Care in Cancer Unit at the Fondazione IRCCS Istituto Nazionale Tumori of Milano (17) between September 2013 and March 2014. The study is part of a larger project on hope, needs, and spirituality assessment in patients undergoing supportive care therapies (18).

Briefly, three hundred outpatients attending the Supportive Care in Cancer Unit for the first time were assessed for eligibility against the following inclusion criteria: 1) Aged over 18 years, 2) able to read and understand Italian, 3) a life expectancy > 6 months, 4) Karnofsky Performance Status (KPS) ≥ 70, 5) no severe symptoms which could cause discomfort during the completion of the questionnaires, and 6) signed an informed consent. Individuals with signs/symptoms of cognitive impairment or with severe mental illness were excluded from the study, as were those who had taken part in research using the same set of questionnaires.

The included patients were either cared for by the Oncological or the Haematological Units depending on their primary cancer, and by the Supportive Care Unit team for the management of the adverse effects of cancer and/or its treatments (i.e. administration of hydration, parenteral nutrition, blood transfusions, denosumab/ bisphosphonates, and/or antibiotics, antimycotics, antivirals, treatments of metabolic alterations etc) (17).

Procedure

Socio-demographic data were obtained through use of a standardized self-report questionnaire. This included self-report of demographic variables including participant age, gender, civil status, education, employment, religious attitude (practicing believer, non practicing believer, non believer). Clinical information was obtained directly from the oncologists working in the Supportive Care Unit, and included: phase of the disease (diagnosis/treatment/follow-up/rehabilitation, metastasis/relapse), type of primary tumor, oncologic treatment received in the last three months (chemotherapy only/radiotherapy only/ surgery only/ hormonotherapy only, mixed), Karnofsky Performance Status (KPS), previous referral to a psychologist, and the presence or absence of a GP for disease referral.

Unmet needs were measured with the NEQ (19, 20) a self-administrated questionnaire developed and validated by the Psychology Unit of the Fondazione IRCCS Istituto Nazionale dei Tumori in Milano. The NEQ is composed of 23 dichotomous (present/absent) items. Item 9 (*I need my symptoms to be better controlled)* was excluded from the following analyses in keeping with the 5-factor model suggested by Annunziata et al. (21). Items were considered at the level of both individual needs and grouped into one of five need domains: information needs (item 1-8, plus item 13) care/assistance needs (item 10-12), relationship needs (item 21-23), psychological support needs (item 17-19), and material needs (item 14-16). Subdivision into domains enhances the psychometric properties of the NEQ making it well suited for use in the cancer context. For each domain a NEQ area-specific score was computed by counting the YES-answers and was treated as an ordinal variable.

The ESAS was developed and validated for use in daily symptom assessment of palliative care patients (22) and has been psychometrically validated for use in the Italian language (23). It includes nine symptoms: pain, tiredness (fatigue), nausea, depression, anxiety, drowsiness, appetite, feeling of well-being and shortness of breath, each assessed on an 11-point Numerical Rating Scale (0 = no symptom; 10 = the worst symptom). An optional tenth symptom can be added by the patient/participant. Anxiety and depression scores derived from the ESAS were used for the present study since these two ESAS items (cut-off for each item=4) were proven to be useful and easy to use for measuring anxiety and depression in nonadvanced cancer patients (24).

Patients with missing information in one or more of the above described assessments were excluded from the subsequent data analyses.

Ethical considerations

The study was granted approval by the Independent Ethical Board of the Fondazione IRCCS Istituto Nazionale Tumori of Milano on 17 September 2013 (N. INT 129/13). Only patients who read and signed the consent form were included.

Data analysis

The number of items reported as an unmet need (i.e. YES answers) were counted and treated as an ordinal variable. The score on the two ESAS items for anxiety and depression were also treated as ordinal variables. Due to the non-parametric nature of the data, Mann Whitney U, Kruskall-Wallis H, and Tamahane *post hoc* tests were used to test for differences based on socio-demographic and clinical characteristics. Correlations between needs and distress outcomes variables were tested using Spearman's rank-order correlation tests. Finally, multiple regression models were run to predict anxiety and depression as a function of all the variables shown to be significantly correlated with emotional distress, including unmet needs. All statistical analyses were performed using SPSS version 20. Differences were considered statistically significant where $p < 0.05$ (two-tailed).

Results

Data analysis was carried out on the 258 patients without missing data. Socio-demographic characteristics and clinical features are reported in Table S1 (Supporting Information). In summary, the sample was evenly split in terms of gender (53.9% males; 46.1% females) with a median age of 59.9 (range 19-89). Half of the sample (49.6%) was retired and the majority (87.2%) declared themselves as having a religious or spiritual belief. Two thirds of participants (66.7%) were undergoing active anti-cancer treatment. Metastatic patients represented only 8.5% of the sample. Tumour types were very heterogeneous and patients were subdivided in two main groups: solid tumours (58.1%)

and haematological malignancies (40.3%). Karnofsky performance status was ≥ 80 in 96% of the patients.

Response frequencies for single NEQ items are reported in Table 1. The two most frequently reported needs were (i) the need for better services from the hospital (42.2%) and (ii) the need for more information about future health concerns (42.6%). The need to speak with people with the same condition (31.8%) was also frequently endorsed.

Self-reported levels of anxiety and depression were low (see Table S2 of Supporting Information): only 27.2% and 17.5% of patients respectively reported anxiety and depression levels above the cut-off used for screening emotional distress (item score ≥ 4) [24]. Anxiety and Depression ESAS score were strongly inter-correlated (*rs*.599, $p < 0.001$).

We used non-parametric correlation tests to explore our hypothesis of a direct correlation between participants' unmet needs in each NEQ domain and levels of anxiety or depression. Statistically significant positive correlations were observed for all types of needs (see Table 2) except for care needs, which did not significantly correlate with either anxiety (*rs* = 0.109, *p*= 0.079) or depression (*rs* = 0.089, *p* = 0.154).

Table 3 presents data on the statistical impact of socio-demographic and clinical variables on unmet needs and emotional distress (only statistically significant ($p<0.05$) or borderline *s*ignificant ($p<0.06$) associations are reported). Females had significantly (*p<.01*) higher levels of anxiety and depression, and there were statistically significant negative correlations between age and psycho-emotional and material needs (r_s=-.133 and -.204, respectively). Higher relationship needs were reported among participants who were currently unemployed (*p*<.05). Patients who reported previous consultation with a psychologist had significantly ($p < .01$) higher levels of depression (*p*= .001) and anxiety (*p*= .002) compared to those who never sought counselling. Psycho-emotional needs were

also significantly higher in patients who reported a previous referral to a psychologist, even if not necessarily for their cancer related concerns (p<.001). Performance status negatively correlated with both anxiety (p= .019) and depression (p= .017), and care (p= .012), relational (p= .053) and psycho-emotional (p=. 052) needs. The type of tumor instead significantly impacted on material needs which were higher in patients diagnosed with hematologic tumors (p= .025).

The socio-demographic variables, clinical factors and unmet needs found to be significantly correlated with either anxiety or depression in these bivariate analyses, were then entered into one of two multiple regression models to test their independent association with anxiety or depression (see Table 4). 20% of the variance in anxiety was predicted by the regression model, however performance status and referral to psychologist failed to significantly contribute at the individual variable level. The regression model for depression was able to account for just 11% of the variance in depression levels; overall unmet needs, gender and previous referral to psychologist each explained a significant amount of the variance in self report scores, however, performance status was not a significant contributor.

Discussion

To ensure good patient-centered care, emotional and psychosocial factors should be considered alongside physical symptoms and outcomes (25). Studies on emotional distress in cancer patients, report on average a prevalence of depression and anxiety ranging from 8 to 24% (26, 27). Our findings are consistent with these prevalence data, although a direct comparison between studies is difficult due to recruitment of different patient samples and use of different assessment tools. Overall, one in four patients in this study had anxiety levels at the ESAS > 3, and one in six patients had an equivalent level of depression: this level has previously been demonstrated to be a useful cut-off score for

anxiety and depression screening in nonadvanced cancer patients (24). Therefore, our study confirms the importance for distress screening so that anxiety and depression can be recognized and treating effectively to reduce the human cost of cancer (28).

Approximately one third of patients recruited into this study reported unmet psychosocial and supportive care needs, such as the desire to speak with people undergoing the same type of experience. Indeed relationship needs are frequently reported in the literature (19, 20) with similar frequencies. Thus, the reported data highlight a gap in the care system and support the need of a stronger collaboration with professionals from the Clinical Psychology departments into the routine clinical care of cancer patients.

The present sample included nonadvanced cancer patients in various different phases of their treatment trajectory. This might affect emotional distress since it is well known that psychological adaption naturally occurs during emotional stress and the majority of individuals possess at least some ability to psychologically cope with differing stress levels. Individual variation in adaptation capacity and coping will undoubtedly affect levels of anxiety and depression during cancer treatment. Therefore, it may be expected that emotional distress measures are not constant during the treatment trajectory (29), and it was unfortunate that we did not have access to longitudinal data to explore the effects of such time-related changes or inference of causality in this sample.

Overall, statistically significant positive correlations were found between all need domains (except for care needs) and both anxiety and depression, thus confirming our initial hypothesis. However, although correlations were statistically significant, the correlation coefficients were low. This could be viewed as a limitation of our data, but the small correlation resulting from multidimensional constructs is common to psychological research (30).

We provide evidence in this paper for the fact that social-demographic and clinical data could constitute a starting point for the prediction of unmet needs. The findings suggest a different level in reported unmet needs according to age, especially for material and psycho-emotional needs, which were lower in older patients, confirming other published data (31, 32). It is important that in screening for distress and unmet needs, particular attention is given to monitoring elderly cancer patients, since these are at high risk and are the least prone to spontaneously expressing their needs (33). Unlike previous research, no gender-related differences in unmet needs were observed (31, 32).

Other interesting and statistically significant links were found between type of tumour and material needs. This point warrants further research as the natural history of the disease is very different between solid and haematological tumours. Indeed, haematological tumours are often treated with more aggressive chemotherapy protocols and patients experience alternate cycles of remission and relapse, which can be emotionally difficult to cope with; these differences may well explain the significant differences observed in this study (34).

Study evaluation

A possible limitation of this study is that emotional distress assessment was based on self-report questionnaires, which although validated, are not the most sensitive method of diagnosing either anxiety or depression (35). However, if one considers the widespread underdiagnoses of mood disorders in cancer patients (36), the ESAS might still be regarded a useful screening tool, which might help improve the clinical management of cancer patients (24). In fact, the ESAS offers a reasonable alternative to more complex assessment tools with the additional advantage of assessing not only psycho-emotional aspects. The use of ESAS in the context of cancer support care is further supported by its ease of administration, easy scoring, and the relative speed in completion, which avoids burdens to participants (35).

The possibility that our findings are biased by geography cannot be excluded since we recruited from one single site. Although this clinical site – a Comprehensive Cancer Center in Italy – provides care to patients from many different areas, this study includes only outpatient attendees, who need, therefore, the financial means (living expenses, travel, and accommodation) to attend the clinic.

An additional limitation of this study (as mentioned earlier) is the use of a cross-sectional design. A longitudinal study would have allowed us to disentangle the relationship between anxiety/depression and unmet needs, and make inferences about causality. However, we believe that cross-sectional studies like this are still important for as first steps towards planning better organization of care for cancer patients.

Conclusion

Emotional distress has been defined as the sixth vital sign (alongside respiration, heart rate, blood pressure and pain (37) in cancer care, implying its importance in a patient-centered health care model. Supportive care units are the most appropriate context for gaining a broad picture of cancer patients unmet needs and of the impact of the gaps and problems in care delivery. It represents the ideal setting for studies on the psycho-emotional aspect too, since such units provide a holistic approach to care, giving support to patients and their families, and access to other healthcare professionals and informational/educational resources to recognize that cancer stretches far beyond the life-threatening physical symptoms (17). The present study contributes to this important goal by presenting data which can help physicians working in the supportive care oncology setting to recognize patients more likely to develop severe emotional distress at an earlier and more treatable stage. Early recognition of distress symptoms improves quality of life and is associated with greater adherence to treatments resulting in improved survival (16). In this study, we have confirmed that emotional distress and unmet needs are present

among nonadvanced cancer patients and that their assessment should be included in as a routine component of clinical care. However, self-report questionnaires like those used here provide only screening information: it is vital that these are followed by an adequate triage, offered by trained professionals, to identify those patients who might benefit from psychological intervention, and to intervene to meet those needs highlighted.

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Table 1: Response frequencies for the Need Evaluation Questionnaire (NEQ)

Item	**n**	**%**
1 I need more information about my diagnosis	60	23.4
2 I need more information about my future condition	109	42.6
3 I need more information about the exams I am undergoing	48	18.6
4 I need more explanations of treatments.	69	26.7
5 I need to be more involved in therapeutic choices	56	21.7
6 I need clinicians and nurses to give me more comprehensible information	51	19.8
7 I need clinicians to be more sincere with me	33	12.8
8 I need to have a better dialogue with clinicians.	68	26.4
10 I need more help with eating, dressing, and going to the bathroom	28	10.8
11 I need better respect for my intimacy	20	7.7
12 I need better attention from nurses	23	8.9
13 I need to be more reassured by the clinicians	64	24.8
14 I need better services from the hospital (bathrooms, meals, cleaning)	109	42.2
15 I need to have more economic-insurance information (tickets, invalidity, etc.)	75	29.1
16 In relation to my illness I need economic help	40	15.5
17 I need to speak with a psychologist	39	15.1
18 I need to speak with a spiritual advisor	23	8.9
19 I need to speak with people who have this same experience	82	31.8
20 I need to be more reassured by my relatives	30	11.6
21 I need to feel more useful within my family	80	31.0
22 I need to feel less abandoned	39	15.1
23 I need to receive less commiseration from other people	38	14.7

Table 2: Correlation between cancer patients' unmet needs (NEQ) and Anxiety and Depression (ESAS)

Variable	**Anxiety**	**Depression**
	r_s (*p*-value)	**r_s (*p*-value)**
Overall needs	.283 (<.001)	.284 (<.001)
Informative needs	.236 (<.001)	.130 (.037)
Care needs	.109 (.079)	.089 (.154)
Relational needs	.219 (<.001)	.290 (<.001)
Psycho-emotional needs	.214 (.001)	.224 (<.001)
Material needs	.164 (.008)	.181 (.003)

Note. Correlations were evaluated by Spearman's rank correlation test.

Table 3 Association of socio-demographic and clinical variables with unmet needs and emotional distress

	NEQ				ESAS	
	Psycho-emotional	**Relational**	**Material**	**Care**	**Anxiety**	**Depression**
KPS						
70	0.5(1.07)	1.13(1.36)		0.63(1.06)	2.36 (2.37)	1.18 (1.89)
80	0.71(0.84)	0.84(1.09)		0.41(0.76)	2.18 (2.38)	1.55 (1.92)
90	0.6(0.83)	0.71(1.02)		0.22(0.64)	2.27 (2.57)	1.6 (2.31)
100	0.43(0.65)	0.64(1.04)		0.19(0.48)	1.65 (2.49)	1.18 (2.35)
Kruskall-Wallis *p*	0.052	0.053		0.012	0.019	0.017
Psych counseling						
yes	0.98(0.94)				1.8(2.36)	1.17(2.09)
no	0.48(0.72)				3.09(2.79)	2.3 (2.46)
Mann-Whitney p	<0.001				0.002	0.001
Age continuous						
Spearman's r	-1.333		-0.204			
p-value	0.032		0.001			
Religion						
Believer pract.	0.63(0.81)					
Believer no pract.	0.58(0.79)					
Non believer	*0.24(0.5)*					
Kruskall-Wallis *p*	.033					
Employment						
Employed		0.54(0.84)				
Unemployed		1.09(1.16)				
Retired		0.77(1.17)				
Kruskall-Wallis *p*		0.042				
Gender						
Male					1.45(2.2)	1.05(1.95)
Female					2.74(2.74)	1.84(2.52)
Mann-Whitney *p*					0.001	0.008

Mean values (SD)

Table 4 Multiple regression model: p-values for the variables included in the model

Independent variables	Dependent variables	
	Anxiety	Depression
Performance status	0.985	0.518
Referral to psychologist	0.085	**0.015**
Gender	**0.001**	**0.017**
Overall need score	**<0.001**	**<0.001**
Amount of predicted variance*	20%	11%

*when including only statistically significative variables